IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES L.P.
and TCD ROYALTY SUB LP,

Plaintiffs,

v. No. 21-cv-1710

LUPIN INC. and LUPIN LTD.,

Defendants.

Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; Andrew J. Cochran, Gerald J. Flattman, Jr., CAHILL GORDON & REINDEL LLP, New York, New York.

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Counsel for Defendants

MEMORANDUM OPINION

April 11, 2024

BIBAS, *Circuit Judge*, sitting by designation.

In its emergency-injunction motion, Galderma rehashes many of the same arguments that I rejected at trial. Unsurprisingly, that leads to the same result. I deny its motion for injunctive relief.

I. Background

Galderma sells Oracea, a once-daily treatment for rosacea. D.I. 197, at 2. Oracea works by releasing doxycycline in two portions: a 30-mg immediate-release portion and a 10-mg delayed-release portion. *Id.* That maintains consistent steady-state blood levels of doxycycline, staving off rosacea. *Id.*

Hoping to make a generic version of Oracea, Lupin submitted an Abbreviated New Drug Application to the FDA. *Id.* at 3. The application described a drug with a 22-mg immediate-release portion and an 18-mg delayed-release portion. *Id.* at 3. But after the FDA tentatively approved it, Galderma sued Lupin for patent infringement. *Id.* at 4.

After a bench trial, I rejected Galderma's patent-infringement claim. *Id.* at 2, 19. I found that Galderma's sole witness, Dr. Edward Rudnic, was not credible. *Id.* at 11–12. And I concluded that no version of its ever-shifting theory of infringement satisfied its burden by a preponderance of evidence on the main contested issue: whether Lupin's drug contained a 30-mg immediate-release portion and a 10-mg delayed-release portion. *Id.* at 12–17. Rather, I ruled that the trial evidence confirmed that Lupin's drug contains a 22-mg immediate-release portion and an 18-mg delayed-release portion. *Id.* at 17.

Undeterred, Galderma now wants injunctive relief. It asks for an injunction to stop Lupin from manufacturing, marketing, selling, or using its generic drug during Galderma's appeal. Pls.' Emergency Mot. 1 (relying on 35 U.S.C. § 283 and Fed. R. Civ. P. 62(d)). It also asks for a temporary restraining order. *Id.* (relying on Fed. R. Civ. P. 65(b) and Fed. R. App. P. 8(a)).

II. Injunctive Relief Is Not Warranted

"An injunction pending appeal is extraordinary relief … [that is] within the discretion of the district court." *Cipla Ltd. v. Amgen Inc.*, 2019 WL 2053055, at *1 (D. Del. May 9, 2019) (internal quotation marks omitted). To decide whether to grant injunctive relief here, I consider the usual four factors:

(1) Has Galderma made a strong showing that it is likely to succeed on the merits?

(2) Will it be irreparably injured without an injunction?

(3) Will the injunction substantially injure other interested parties?

(4) Does the public interest favor an injunction?

Hilton v. Braunskill, 481 U.S. 770, 776 (1987). To get an injunction, the moving party must show "*both* of the first two factors." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). But because Galderma has shown neither, I deny its requested relief.

A. Galderma cannot show a likelihood of success on the merits

A likelihood of success cannot be "shown if an alleged infringer raises a substantial question regarding … infringement." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015). Lupin has raised more than a substantial question about an essential element of infringement—the amount of its immediate- and delayed-release portions. So Galderma cannot show a likelihood of success on the merits.

To resist this conclusion, Galderma makes five arguments. All fail.

First, it argues that the Opinion incorrectly found that pH 4.5 is not biorelevant for a fasted stomach. Opening Br. 4. But its own evidence undermines its position:

The Kalantzi article, relied on by Dr. Rudnic at trial and Galderma in this motion, says that "the generally accepted value for fasting gastric pH … is usually measured to be about 2 or slightly lower." PTX-149, at 5–6. It also notes that when it did find higher stomach-pH values, "in most cases they probably reflect the dilution of gastric contents with saliva and/or nasal secretions." *Id.* at 5. And Galderma's entire theory of patent infringement relies on the behavior of Lupin's capsules at pH 4.5 (plus bioequivalence data). Thus, to win on appeal, it must prove that my factual finding on that point was clearly erroneous—a tall task.

Galderma also asserts that the Opinion improperly placed a thirty-minute cut-off between immediate and delayed release. Opening Br. 5. But even if that were true, it was harmless because I evaluated Galderma's theory at every time in the two-stage test that it suggested. *See* D.I. 197, at 16 (discussing doxycycline release at 30 minutes, 1 hour, and 2 hours after exposure to pH 4.5).

Second, Galderma argues that the Opinion misapplies Hatch-Waxman case law and "errs as a matter of law by dismissing the controlling data submitted in Lupin's [application]." Opening Br. 6. But I already considered and rejected those legal arguments in the Opinion. D.I. 197, at 15–17. And I explained in detail why a person of ordinary skill in the art would not have relied on the second stage of one test in Lupin's application to prove patent infringement, especially when Oracea's data displayed errors. *Id.* at 12–15.

Third, Galderma contends that I improperly considered results from Lupin's small batch manufactured during this litigation. But I have repeatedly addressed

and rejected this argument. *See* D.I. 152; D.I. 197, at 15–16. And even if it were error for me to consider the small batch, the testing on that batch merely reinforced the lack of patent infringement. *See* D.I. 197, at 15 ("Lupin gave yet another *clue* by doing more testing." (emphasis added)). So Galderma finds no succor in this argument either.

Fourth, Galderma claims that the Opinion "disregards … that even one instance of infringement is sufficient." Opening Br. 10. On its face, this claim is incredible: the Opinion stated that "if I credited that Capsule 1's behavior at 30 minutes into the second stage reflects *in vivo* behavior at that time in the stomach, Galderma would have shown infringement." D.I. 197, at 17. Galderma then plays a shell game, arguing that Judge Stark found "*in vitro* testing at the 30-minute time point is factually relevant." Opening Br. 10. I agree. But the testing Galderma relies on was 30 minutes *into the second stage*—in other words, at 150 minutes. *See* D.I. 197, at 7. And Galderma did not show that the *in vitro* test results in that second stage reliably correlate to results in the body.

Fifth, Galderma says that the Opinion disregards evidence of infringement based on mean release at later time points. Opening Br. 12. Not so. Rather, I simply did not find that its evidence supported infringement under the doctrine of equivalents. *See* D.I. 197, at 17–18. And Galderma cites no law to support this argument.

In sum, Galderma repeats many of the same arguments that I found thoroughly unconvincing at trial. Most of these arguments rely heavily on factual findings,

meaning they would need to overcome clear-error review. So Galderma has not made a "strong showing" that it is likely to succeed on the merits. *Hilton*, 481 U.S. at 776.

B. Galderma has not shown irreparable harm

The irreparable-harm inquiry looks for "harms that no damages payment, however great, could address." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). For a harm to be irreparable, "[m]ere injuries, … in terms of money, time[,] and energy necessarily expended in the absence of a stay, are not enough." *Sampson v. Murray*, 415 U.S. 61, 90 (1974).

Lupin argues that things have changed because it launched its drug. Updated Resp. Br. 14. Though it was within its rights to do so, it launched its drug while this emergency motion was pending and in an apparent attempt to change the status quo. I will not reward such gamesmanship by considering Lupin's argument on that point.

For its part, Galderma makes various arguments for irreparable injury, including: (1) losses in sales and market shares; (2) net price erosion from Lupin's entry; (3) loss of preferred status with Pharmacy Benefit Managers; (4) disruption to their workforce; (5) loss of research and development efforts; and (6) harm to reputation and loss of goodwill. Opening Br. 12–13.

Even accepting that Lupin's drug will cause the first three injuries, Galderma cannot show that they are irreparable. True, an independent generic entering the market will likely cause a decline in price and sales for Oracea. D.I. 204-1, at ¶ 38. But "branded drugs have been able to return to their long-term sales and prescriptions trends once exclusivity has been restored." D.I. 216-25, at 3. Plus, "courts have routinely decided that market share and price erosion do not amount to irreparable

harm." *King Pharms., Inc. v. Sandoz, Inc.*, 2010 WL 1957640, at *5 (D.N.J. May 17, 2010). And Galderma has already authorized a generic of Oracea. D.I. 204-1, at ¶ 15. So I credit the declaration of Lupin's expert that the losses suffered by Galderma would be quantifiable. D.I. 214, at ¶¶ 27, 58–61.

Nor does Galderma show that disruption to its workforce or loss of research and development will cause irreparable injury. True, a "potential reduction in work force" can be an irreparable injury. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). As can loss of business opportunities, such as decreased research and development. *Celsis*, 664 F.3d at 930. But neither *always* amounts to irreparable injury. *See, e.g.*, *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666, 682 (D.N.J. 2007) (rejecting irreparable harm based on "loss of research opportunities [and] reduction in workforce"). Plus, in 2023, Galderma had over $4 billion in sales, of which Oracea is less than fifty million. D.I. 214, at ¶ 52; D.I. 204-1, at ¶ 36. And Galderma does not show how many employees work solely on Oracea or what research and development opportunities it might lose due to Lupin's drug. D.I. 214, at ¶¶ 51, 53. These losses are thus speculative at best.

Finally, Galderma argues that it might suffer reputational damage because of quality issues with Lupin's product. Opening Br. 16. It gives the example of a generic rosacea cream that caused adverse events incorrectly attributed to the patented cream. *Id.* But that is a different drug. And Galderma points to nothing showing that

Lupin's drug would cause such adverse events. So I find that alleged injury speculative too.

"[D]elay [also]… militates against the issuance of an … injunction by demonstrating that there is no apparent urgency." *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995). And Galderma delayed: After closing arguments on February 22, 2024, I told the parties the outcome of the case. D.I. 193, at 49–55. Then, on March 22, 2024, I issued the Opinion to the parties under seal. D.I. 197. Still, Galderma waited until April 4, 2024, to file this emergency motion—three days before Lupin could get final approval from the FDA. Opening Br. 2. Though Galderma argues that the final judgment was not entered until April 1, that judgment contains what it already knew a month and a half earlier.

In sum, Galderma's "irreparable" injuries are either quantifiable or speculative. And its delay weighs against irreparable injury. So I find no irreparable injury.

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Galderma shows neither a likelihood of success on the merits nor irreparable injury. But it needed to show both. Thus, I reject its request for the potent relief of an injunction or temporary restraining order.